FEB 2 0 2014

Wright Medical Technology, Inc.
5677 Airline Road Arlington, TN
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510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the INBONE® Total Ankle System Line Extension.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002
Date:	December 3, 2013
Contact Person:	Val Myles Regulatory Affairs Specialist I Office - (901) 290-5162 Fax – (901) 867-4190
(a)(2). Proprietary Name:	INBONE® Total Ankle System
Common Name:	Ankle Prosthesis
Classification Name and Reference:	21 CFR 888.3110 – Class II
Device Product Code, Device Panel:	HSN: Ankle Prosthesis
(a)(3). Predicate Device:	K123954 INFINITY™ Total Ankle & K100886 INBONE® II Total Ankle System

(a)(4). Device Description

The INBONE® implant is a total ankle replacement (TAR) that is made of several specific components. A key concept of the INBONE® device is its modularity. Based on patient anatomy, a number of component sizes can be optioned for best fit. These components include the tibial stem components, the tibial tray, the poly bearing, the talar dome, and the talar stem.

(a)(5). Intended Use

The INBONE® Total Ankle is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. The INBONE® Total Ankle is additionally indicated for patients with a failed previous ankle surgery. CAUTION: The ankle prosthesis is intended for cemented use only.

(a)(6). Technological Characteristics Comparison

The INBONE® Total Ankle Line Extension is technologically substantially equivalent to the predicates. A summary of the changes is shown below:

- Addition of a Size 1 Talar Dome and Size 1 + Poly Bearing
- Addition of thicker poly bearings for revisions
- Trials for all of the poly bearings in this line extension and the size 1 talar dome
- Mid and top tibial stem pieces with the plasma coating removed

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Performance testing and engineering analysis related to articular shear stability, contact pressure, and the lock detail supports the equivalence of the subject device and shows that no new worse-case devices are introduced in this system. The safety and effectiveness of the INBONE® Total Ankle Line Extension is adequately supported by the testing rationales, substantial equivalence information, materials information, and comparison of design characteristics provided within this premarket notification.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system do not affect the safety or effectiveness of the system. From the evidence submitted in this 510(k), the subject devices can be expected to perform substantially equivalent to the predicate system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 20, 2014

Wright Medical Technology, Incorporated
Val Myles
Regulatory Affairs Specialist I
5677 Airline Road
Arlington, Tennessee 38002

Re: K133585
Trade/Device Name: InBone® Total Ankle Line Extension
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: January 16, 2014
Received: January 24, 2014

Dear Val Myles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133585

Device Name
INBONE® Total Ankle Line Extension

Indications for Use *(Describe)*

The INBONE® Total Ankle is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

The INBONE® Total Ankle is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: The ankle prosthesis is intended for cemented use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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